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SYRINGE

Field of the invention

The present invention relates to a syringe, and more particularly, to one that is able to perform some functions automatically, for instance a self-filling function and/or an automatic retraction of the needle.

Background

There has been an increased awareness concerning the potential for transmission of diseases such as acquired immune deficiency syndrome (AIDS) by way of accidental needle sticks from contaminated used needles or through the sharing of used needles by drug-users.

Healthcare workers come into contact with spent needles possibly hundreds of times, daily throughout the course of their work. There have been a lot of efforts in hospitals to educate hospital personnel to take every possible precaution to prevent needle stick injuries and to take appropriate medical treatment after a needle stick. However, a more fundamental solution to prevent such accidental injuries is to develop a new syringe with improved features, which eliminate the operation procedures mostly responsible for such injuries. Furthermore, the Needlestick Safety and Prevention Act in the USA requires all healthcare workers to use safety syringes to prevent accidental needle stick injuries. Therefore, most hospitals and clinics in the USA prefer to use automatically retractable safety syringes, which retract the needle into the body of the syringe after use and can be used one-handed. These are more convenient and safer than the two-handed manual retractable syringes.

A number of different devices have been proposed for disabling a syringe and/or needle in order to minimise the risk of contamination from a used syringe.

In general, a typical syringe comprises a hollow syringe body with a needle mounted at one end of the body. A plunger with a piston at one end is slidably mounted into the syringe body such that the end of the plunger can be depressed into and withdrawn from the hollow body of the syringe.

There are numerous devices for preventing a needle from coming in contact with human skin. These devices generally fall into two categories.

The first of the two categories involves sheathing a needle with an extra plastic tube. This tube is slidable axially along the outside of the syringe body and can be locked in the desired position to prevent the sharp end of the needle from sticking whoever is using or disposing of the syringe.

The second category relates to a syringe having a device for retracting the needle into a syringe barrel after use, in order to eliminate the need for recapping the needle after the syringe is used.

US Patent No. 5,344,403, issued to Rahnfong Lee on 6 September 1994, relates to a retractable safety syringe comprising a hollow body, a plunger and a needle carrier. A hub attached to an end of the plunger engages the needle carrier when the plunger is depressed, so that the needle carrier is retracted into the hollow body of the syringe along with the needle when the plunger is withdrawn. A sharp notch at the rear of the barrel catches the hub as the plunger is withdrawn, to allow the plunger shaft to be broken off. After the plunger shaft is broken off, the needle will remain trapped within the syringe.

International Patent Application Publication No. WO-A-01/64,272, published on 7 September 2001 in the name of Teng Jun Piao, relates to a syringe having a retractable needle. The needle is mounted onto a needle carrier. The end of the syringe plunger engages the needle carrier when it is fully depressed into the barrel of the syringe. As the plunger is withdrawn, it withdraws the needle carrier into the barrel of the syringe, at an angle. This prevents the needle being pushed back out again. Instead it catches on a protruding surface and is deformed to be of no use. In addition, the plunger includes a fragile portion that causes a portion of the plunger to break when the plunger is withdrawn. Thus, the syringe cannot be re-used.

However, for such syringes, the withdrawal of the needle into the barrel of the syringe is entirely manual and requires a user to remember to make some deliberate movement to withdraw the needle into the syringe.

A variation of this theme is to enable the needle to be retracted automatically into the barrel of the syringe.

US Patent No. 4,966,593, issued to James J. Lennox on 30 October 1990, relates to a single-use syringe having a needle which is automatically retracted within the barrel of the syringe after use. A release mechanism incorporating a spring is used to cause the needle to be retracted wholly into the barrel. However, a user is required to give an extra push to the plunger after administering the injection in order for the release mechanism to be actuated.

International Patent Application Publication No. WO-A-98/58,694, published on 30 December 1998 in the name of Teng Jun Piao, relates to a single-use syringe using two springs that are attached to an end of the syringe and to a plunger to induce automatic withdrawal of the needle into the barrel of the syringe. The springs are in an extended state when the plunger is depressed. At this position the plunger engages the needle carrier holding the needle. When the plunger is released, the springs return to their neutral, non-extended state. This reverse spring force causes the plunger to be withdrawn automatically. As a consequence the needle carrier holding the needle is also retracted into the barrel. Further, a portion of the plunger can be easily broken off after use to prevent the syringe from being re-used by someone else.

However, the syringes described in the above-mentioned documents are either too complicated in their construction, or have too many precision components, which increase the overall cost of the syringe. An economic automatic retractable and non-reusable syringe is urgently required in the market.

Summary of the Invention

According to an aspect of the invention, there is provided a syringe comprising: a body, a plunger, a first sealing member and a second sealing member. The body has a first end for mounting a needle, a second end, and an internal bore extending from the first end to the second end. The plunger has a first end mounted slidably within the bore of the body, with a second end of the plunger extending out of the second end of the body. The first sealing member is on the plunger, extending into sliding sealing engagement with the bore. The second sealing member seals against the body, positioned between the first sealing member and the second end of the body, and

extending into sliding sealing engagement with the plunger. The first and second sealing members, the body and the plunger are arranged such that depressing the plunger within the bore, towards the first end of the body, generates a vacuum between the first and second seal members.

According to another aspect of the invention, there is provided a plunger for a syringe, comprising: a shaft portion, a first sealing member, a pushing portion and a second sealing member. The shaft portion has a first external diameter. The first sealing member is fixedly mounted on a first end of said shaft portion, the first sealing member having a second external diameter larger than the first external diameter. The pushing portion is fixedly mounted on a second end of said shaft portion, the pushing portion having a third external diameter larger than the second external diameter. The second sealing member slidably mounted on said shaft portion, the second sealing member having a fourth external diameter substantially the same as the second external diameter.

According to another aspect of the invention, there is provided a method of using a syringe, comprising depressing a syringe plunger into a syringe body. The syringe plunger carries a first seal member which slidably seals against the syringe body. The syringe plunger sealably slides against a second seal member. Depressing the syringe plunger into the syringe body moves the first and second seal members apart. Moving the first and second seal members apart generates a vacuum between the first and second seal members.

Brief Description of the Drawings

The invention will now be further described by way of non-limiting example, with reference to the accompanying drawings, in which:-

Figure 1 shows an exploded view of a syringe in accordance with a preferred embodiment of the invention;

Figure 2a shows a sectional view A-A of the body portion of the syringe in Figure 1;

Figure 2b shows a sectional view B-B of the plunger portion of the syringe in Figure 1;

Figure 3 is a flowchart showing the sequence of steps used in the operation of the syringe of Figure 1;

Figure 4 shows the syringe of Figure 1 with the plunger fully retracted;

Figure 5 shows the syringe of Figure 1 at the end of an insertion stroke, just before a fluid is withdrawn into the syringe;

Figure 6 shows the syringe of Figure 1 in a condition in which fluid has been drawn into the syringe body;

Figure 7 shows the syringe of Figure 1 with the plunger fully depressed into the syringe body and the needle carrier engaging with the piston, at the end of an injection stroke;

Figure 8 shows the syringe of Figure 1 with the needle fully retracted into the syringe body; and

Figure 9 shows the syringe of Figure 1 with a portion of the plunger broken off.

Detailed Description

Figures 1 to 9 relate to a syringe according to an embodiment of the invention. The syringe has a hollow body 10 with an internal bore, a plunger 20 slidably mounted in the body and a needle 44 mounted at a first end of the body. A first sealing member 30, at a first end of the plunger 20 and within the body, slidably seals against the body. A second sealing member 60 seals against the body and slidably seals against the plunger shaft 22, the second sealing member being positioned between the first sealing member 30 and a second, opposing end of the body (although it does itself extend to that second end). Pushing the plunger 20 into the body 10 creates a vacuum between the first and second sealing members 30, 60. This can be used to draw liquid into the syringe for injection. Alternatively, the vacuum can be used to retract the needle 44 automatically into the body, if the plunger 20 is first pushed in a sufficient amount. A portion of the plunger 20 is easily broken off after use to ensure that the syringe cannot be re-used.

Figure 1 shows an exploded view of a syringe of an embodiment of the present invention. Figures 2A and 2B show sectional views along the lines A-A and B-B, respectively, of the syringe in Figure 1 with various parts assembled.

The syringe is made up of two main components, a body 10 and a plunger 20. The syringe body 10 is hollow, with an internal bore and generally elongate and cylindrical in shape. The syringe body 10 has a neck 13 at a first, distal end with the

external diameter of the neck being smaller than that of the barrel of the body 10 and the internal diameter of the neck being smaller than that of the main bore of the body 10. The plunger 20 is slidably mounted within the syringe body 10 through a hole in the second, proximal end of the syringe body 10.

An annular finger flange 11 is provided at the proximal end of the syringe body 10. The finger flange 11 extends outwards from an external surface of the syringe body 10, to provide a support surface for a user's fingers when using the syringe. A shallow annular stop flange 12 projects inwardly into the hollow inside the syringe body 10 from an internal surface, near the proximal end of the syringe body 10.

An annular luer 50 is mounted internally on the neck portion 13 of the syringe body 10. The luer 50 is hollow and generally cylindrical in shape and has a hollow tapered nozzle 55 and an outer wall portion 58. An annular cavity 54 is defined between an inner surface of the outer wall portion 58 and an external surface of the nozzle 55. The luer 50 is mounted within the neck 13 of the syringe body 10 by means of annular lip members 52, 53 that are axially spaced on an external surface of the outer wall portion 58. The lip members 52, 53 engage with corresponding notches 131 on an internal surface of the neck 13. A tapered annular supporting lip 51, extending outwards at the proximal end of the luer 50, engages with the internal surface of the syringe body 10 at a tapered section 15 between the neck 13 and the main hollow barrel portion of the syringe body 10. The annular lip members 52, 53 and the supporting lip 51 serve to hold the luer 50 within the neck 13 and also to prevent fluid from leaking out of the syringe.

A needle 44 is mounted on a needle carrier 40 at the distal end of the syringe body 10. The needle 44 is mounted on the needle carrier 40. The needle carrier 40 is hollow and generally conical in shape. An external annular rib 41 extends from the base of the needle carrier 40. The needle carrier 40 is fitted into the annular cavity 54 of the luer 50 to allow fluid communication between the needle 44, the needle carrier 40 and the syringe body 10. The needle carrier 40 is held in place by frictional force between the inner surface of the outer wall portion 58 of the luer 50 and the rib 41 of the needle carrier 40 and between the inner surface of the needle carrier 40 and the outer surface of the nozzle 55. The luer 50 serves to hold securely the needle carrier 40 at the distal end of the syringe body 10 and to seal the needle carrier 40 to the syringe body 10. With the needle carrier 40 mounted on the luer 50, a recess 265 extends forwards of the distal end of the luer nozzle 55 to the inner surface of the needle carrier 40.

The needle carrier 40 and the luer 50 together form a needle holder for the syringe.

The plunger 20 comprises a piston assembly 201, including a first sealing member exemplified here as a gasket 30, a generally cylindrical shaft 22 and a second sealing member, exemplified here as a an annular seal 60 mounted on the shaft 22. A flanged push-button 21 is provided at a proximal end of the shaft 22. The push-button 21 serves as a support surface for the user to push on or pull on, to depress or withdraw the plunger 20. A pair of flat portions 242, arranged in a cross, extends in the axial direction from the distal end of the shaft 22 to the piston assembly 201, to connect the piston assembly 201 to the shaft 22.

A disc 25 of the piston assembly 201 is connected to only one of the pair of flat portions 242 and at only two points, to form a break portion 24. The break portion 24 is designed such that the shaft 22 can be easily dislodged from the piston assembly 201 and thereby from the syringe after use. An engaging portion in the form of an elongate protrusion 261 having a pair of resilient members 262 at its distal end extends forwards from the disc 25. A tip gap 263 between the two resilient members 262 allows the resilient members 262 to be compressed together. The resilient members 262 have detents 264 at their distal ends. The detents 264 have tapered front ends extending outwards in the rearward direction. The detents 264 extend rearwards a short distance before ending with a rearward facing laterally extending surface. A radial flange 253 extends from the elongate protrusion 261, a short distance from the disc 25.

A gasket 30 is mounted over the elongate protrusion 261, which extends through the centre of the gasket 30 and out through a gasket through-hole 33. The gasket 30 is mounted against the forward face of the disc 25. The gasket 30 is secured in position by means of an internal groove engaging with the radial flange 253 on the proximal end of the elongate protrusion 261. The gasket 30 is generally cylindrical in shape with a tapering distal end and axially spaced external annular seals 31, 32. The gasket 30, the elongate protrusion 261 and the disc 25 together form the piston assembly 201.

The seal 60 is mounted on the shaft 22. The seal 60 is annular with a cylindrical outer surface of a slightly smaller diameter than the internal surface of the proximal end of the syringe body 10. A pair of axially spaced rib members 62, 63 extend around the

outside of the cylindrical outer surface of the seal 60, to the same diameter (or slightly more) as the internal surface of the proximal end of the syringe body.

For ease of assembly, the shaft 22 is made of two parts, a first portion 22A and a second portion 22B. The seal 60 is mounted over the proximal end of the second portion 22B (as there are no protrusions for it to fit over). After the seal 60 is mounted onto the second portion 22B, the first portion 22A is attached onto the second portion 22B by means of a locating boss 223, on the proximal end of the second portion 22B securely fitting into a corresponding hole in the distal end of the first portion 22A.

A stop member 23 is mounted on the outside of the shaft 22, a first distance forwards of the push-button 21. The first distance is about a fifth of the way along the length of the shaft 22. The distance between the detents 264 and the stop member 23 is slightly more than the distance between the tapered section 15 of the syringe body 10 and the rear surface of the finger flange 11 of the syringe body 10. The slight extra distance is to allow for the thickness of the annular shoulder 61 of the seal 60. The stop member 23 is connected to the outer surface of the shaft 22 through a thin, base portion 231, which allows it to be broken off readily easily.

The syringe body 10, the shaft 20, the disc 25 and the elongate protrusion 261 are made of relatively stiff plastics materials, such as thermoplastic polypropylene. The luer 50, the gasket and the seal 60 are made of elastomeric materials, such as rubber. However, the rubber material used for the luer 50 is usefully be harder than 65 degrees so that the needle carrier 40 can be mounted properly and not fall off when the luer 50 is mounted onto the neck 13.

The first, distal end of the plunger 20 is inserted into the second, proximal end of syringe body 10. The engaging portion is of a small enough diameter to pass into the syringe body 10 without contacting it. The elastomeric gasket 30 is able to deform into the proximal end of the syringe body 10, over the stop flange 12. The disc 25 is stiffer than the gasket, but its circumference is tapered towards the front, which allows it to clip over the stop flange 12.

The seal 60 is securely mounted onto the syringe body 10 at the proximal end of the syringe body 10. The front face of the annular shoulder of the seal 60 abuts the rearward face of the finger flange 11 of the syringe body 10. When inserting the plunger

20 into the syringe body 10, the piston assembly 201 is initially kept as close to the seal 60 as possible, with the disc 25 in contact with the seal 60. This reduces the amount of air initially between the seal 60 and the gasket 30. The second, proximal end of the plunger 20 extends out beyond the second, proximal end of the syringe body 10.

The plunger 20 carrying the piston assembly 201 is slidably mounted within the syringe body 10, from the second, distal end of the syringe body 10. The plunger 20 moves forwards or backwards within the hollow syringe body 10 when the plunger 20 is pushed or withdrawn, respectively. The axially spaced external rib members 62, 63 of the seal 60 seal against the inner surface of the syringe body 10, at the proximal end of the syringe body 10. The further axially spaced internal rib members 64, 65 of the seal 60 slidably seal against the outer surface of the shaft 22.

The axially spaced external annular seals 31, 32 of the gasket 30 slidably seal against the inner surface of the syringe body 10. The gasket 30 and seal 60 provide hermetic seals. When the plunger 20 is pushed into the syringe body 10, the movement of the piston assembly 201 away from the seal 60 generates a vacuum in a vacuum area 202B defined between the piston assembly 201 and the seal 60. It is possibly not a true vacuum, as there may already be some air between the seal 60 and gasket 30 as a result of the assembly of the syringe.

Operation of the syringe is now described in brief with reference to Figures 3 to 9. Figure 3 is a flowchart showing the sequence of steps used in the operation. Figures 4 to 9 are cross-sectional views of the syringe at various points during use.

Initially, at the start step, the syringe is as shown in Figure 4, with the gasket 30 close to the seal 60. In a first step S102, the insertion step, the user pushes the plunger 20 into the syringe body, creating a vacuum between the gasket 30 and the seal 60. At the position shown in Figure 5, the user stops pushing at a first position, step S104, when the stop member 23 abuts the seal 60. The user inserts the end of the needle 44 into a bottle of medical fluid, step S106, and releases the pressure on the plunger, at step S108. The plunger automatically retracts, under the reduced pressure between the gasket 30 and the seal 60, at step S110, to the position shown in Figure 6. This action draws medical liquid into the syringe through the needle 44 and fills the hollow of the syringe body.

The syringe is now ready to give an injection and, at step S112, the user tips the syringe needle uppermost and empties it of air and then inserts the needle into the patient. Then at step S114, the injection step, the user pushes the plunger in again, to inject the medical fluid into the patient. The stop member 23 is pushed to abut the seal 60, and the pushing continues beyond that, at which point the stop member 23 breaks off, step S114. The pushing stops at a second position, at step S116, when the syringe is empty and the engaging means between the plunger and the needle holder engage. In this case the detents 234 extend into the recesses 235 between the luer nozzle 55 and the needle carrier 40, as shown in Figure 7.

As before, pushing the plunger 20 into the syringe body 10 creates a vacuum between the gasket 30 and the seal 60. This time, however, when the user releases the pressure on the plunger 20, at step S118, and the plunger automatically retracts, at step S120, it also retracts the needle holder, including the needle 44, the needle carrier 40 and the luer 50 with it, as shown in Figure 8.

Once the needle 44 is fully retracted, the user is able to snap the shaft 22 off the piston assembly 201, and he does this, at step S122, by bending the shaft 22 down, as shown in Figure 9, thereby rendering the syringe unusable. The process then ends.

The use of the syringe, in particular the drawing of the medical fluid and the retraction of the needle are both easily achieved one handed and automatically.

More specific details of the various points during operation of the syringe are described below, again with reference to Figures 4 to 9.

Figure 4 shows a cross-section of the syringe when the plunger 20 is in a fully retracted state (or not yet depressed state). Some air is trapped in a trapped air area 202A between the piston assembly 201 and the seal 60. The amount of air in the trapped air area 202A is typically of a negligible volume compared to the entire syringe body 10.

In this fully retracted state, only the piston assembly 201 and a small portion of the shaft 20 are within the syringe body 10. The plunger 20 is prevented from retracting further when the disc 25 on the piston assembly 201 comes into contact with the inwardly projecting stop flange 12 near the proximal end of the syringe body 10.

In order to use the syringe, the plunger 20 is pushed into the syringe body 10 to expel most of the air in the syringe body 10 out through the needle 44. This is typically referred to as an insertion stroke. The user is required to exert a manual pushing force to cause the plunger 20 to depress into the syringe body 10. The external annular seals 31, 32 on the gasket 30 of the piston assembly 201 move in sliding contact with the inner surface of the syringe body 10.

As the piston assembly 201 moves away from the seal 60, a vacuum is generated in the vacuum area 202B defined between the piston assembly 201 and the seal 60.

The insertion stroke continues until the position shown in Figure 5. The stop member 23 limits how far into the syringe body the plunger 20 should initially be inserted. The plunger 20 is depressed into the syringe body 10 until the stop member 23 contacts the annular shoulder 61 of the seal 60, at the first position. This marks where the piston has been depressed as far as it is allowed for the user to draw medical fluid into the syringe. At this point, the resilient members 262 protruding from the distal end of the piston assembly 201 are compressed together to fit into the proximal end of the luer nozzle 55. However, the resilient members 262 do not extend fully through the nozzle 55 and thereby can still be withdrawn.

When the pushing force exerted by the user is removed, the plunger 20 is automatically retracted due to the vacuum generated in the vacuum area 202B. This is a low pressure area compared with the pressure on the medical fluid. As the plunger 20 is retracted, the medical fluid is drawn into the syringe body 10 through the needle 44, the needle carrier 40 and the luer 50 into an area between the needle carrier 40 and the piston assembly 201. Depending on the amount of medical fluid required, the user may allow the plunger 20 to retract to its fully retracted state or intercept the retraction of the plunger 20 so as to get a desired more limited volume of medical fluid. Figure 6 shows a cross-sectional view of the syringe in a state when the syringe is filled with the medical fluid. The syringe is now ready for the administration of an injection, through an injection stroke.

When the plunger 20 is pushed forward again into the syringe body 10 at the beginning of an injection stroke, the medical fluid is discharged from the needle 44,

normally into a patient. During the injection stroke, a vacuum is again generated in the vacuum area 202B in the syringe body 10.

Figure 7 shows a cross-sectional view of the syringe at the end of an injection stroke. The plunger 20 is inserted into the syringe body 10 beyond a first, stop position, defined by the stop member 23 contacting the annular shoulder 61 of the seal 60 (i.e. the position at the end of the insertion stroke). The stop member 23 breaks off from the shaft 20 when the user continues to exert a pushing force on the plunger 20 beyond the stop position. When the plunger 20 is inserted beyond the stop position, the resilient members 262 continue all the way through the luer nozzle 55 and extend out through the distal end of the luer nozzle 25. The resilient members are compressed when they are within the nozzle 55, however, once they emerge from the nozzle due to the pushing force, the resilient members 262 revert back to a non-compressed state and the detents 264 extend into the recess 265. If they are pulled rearwards, the detents 264 in the recess 265 engage with the forward facing circumferential edge of the nozzle 55. Thus the luer 50 is connected to the plunger 20. Pushing stops at this second position.

Figure 8 shows a cross-sectional view of the syringe when the needle is retracted into the syringe body. The vacuum generated in the vacuum area 202B during the injection stroke causes the plunger 20 to retract automatically when the pushing force exerted by the user is removed, at the end of the injection stroke. Since the luer 50 is now connected to the plunger 20, the luer 50 together with the needle carrier 40 and needle 44 is retracted into the syringe body 10 as the plunger 20 retracts. The needle carrier 40, together with the needle 44 is completely retained within the syringe body 10. No portion of the needle 44 is exposed for accidental contact. This substantially eliminates the problem of accidental needle sticks during disposal of the used syringe.

After the needle 44 has been fully retracted into the syringe body 10, the shaft 20 is broken off at the break portion 24, as shown in Figure 9. This ensures that the syringe cannot be re-used by another person.

The automatic retraction of the needle 44 into the body 10 of the syringe by means of a vacuum does not require the syringe user to remember to take an extra step to withdraw the needle into the syringe body or to shield the needle 44 with a sheath or the like. This greatly reduces, if not eliminates the problem of accidental needle sticks.

Also, the construction of a syringe of the present invention does not require complicated or costly parts, thus, it can be produced at a relatively low cost.

It will be understood that most of the structure of the above example can be changed without departing from the scope of the invention. For example, the shaft 22 may be hollow. The needle carrier may be integral to the luer 50 instead of being two separate parts. The detents 264 may engage recesses within the luer 50, instead of beyond the luer 50. Engaging means other than detents and recesses may be used between the plunger and the needle holder. The needle 44 can be non-central. The needle 44 can be pulled back into the syringe body 10, at an angle, to make it less easy to pull out. Various ribs, lips and external seals are mentioned in the above description as being axially spaced. They can be spiral if desired, as can corresponding opposing grooves where present; other shapes are also possible, as long as seals are maintained where needed. The plunger shaft is shown as circular in cross-section, but it can be elliptical, as long as a seal is maintained with the seal member 60.

The above described embodiment shows both the drawing of the medical fluid and the retraction of the needle being carried out automatically. The ability for this to operate automatically depends on the quality and size of the vacuum formed between the gasket and seal member. There may be embodiments and times where the vacuum is insufficient for either or both operations. Therefore the user may have to provide some pull to the plunger. However it would be less than might normally be required and may still, possibly be provided one handed. Moreover, the user is not forced to use the syringe as described. He can use it as a normal syringe (whilst being careful about how far the plunger is initially depressed).

Whilst the background of the invention particularly concentrates on avoiding needle stick by retracting the needle, this invention is not limited to having a retractable needle. The invention may involve merely the automatic filling of the syringe. This alone may help prevent some needle stick incidents. Even if it does not, it is still an improvement over the prior art as it involves less effort to use, whilst being very simple. Many other variations are possible within the scope of the present invention which is only limited as defined in the claims or elsewhere as indicated.